Medical Development Program

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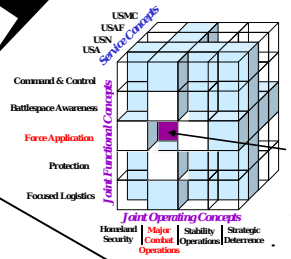
Capabilities-based Process

- **Top-down guidance**
- **Joint Concepts enables the warfighter to shape and influence the trade space debate**
- **Provides the "trade space" discussion at the right level**

Policy
Strategic Planning Guidance/ National Military Strategy

Operational Availability
Assess end of program Forces in warfighting scenarios

Concepts

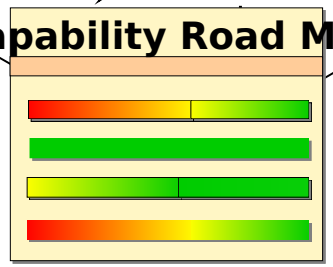


Capability Assessment
Functional Area *
Functional Needs*
Functional Solution

Assess Program
Assesses potential programmed capabilities in an warfighting operational context

Deliver
Provide Operational Capability with fielded Systems to meet a Capability Gap

Capability Road Map



Process decomposes from Policy Guidance to Warfighting Concepts to Capability Areas to Potential Solutions (material & non-material) to Products

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Joint Warfighting Concepts

Joint does not mean the solution has to be SAME

Despite heroic efforts, some Joint Warfighting Concepts have met with limited success during experimentation.

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Joint Capability Integration and Development System (JCIDS)

Goal: Provide the Joint Force with the capabilities needed to perform across the range of military operations and challenges.

Through:

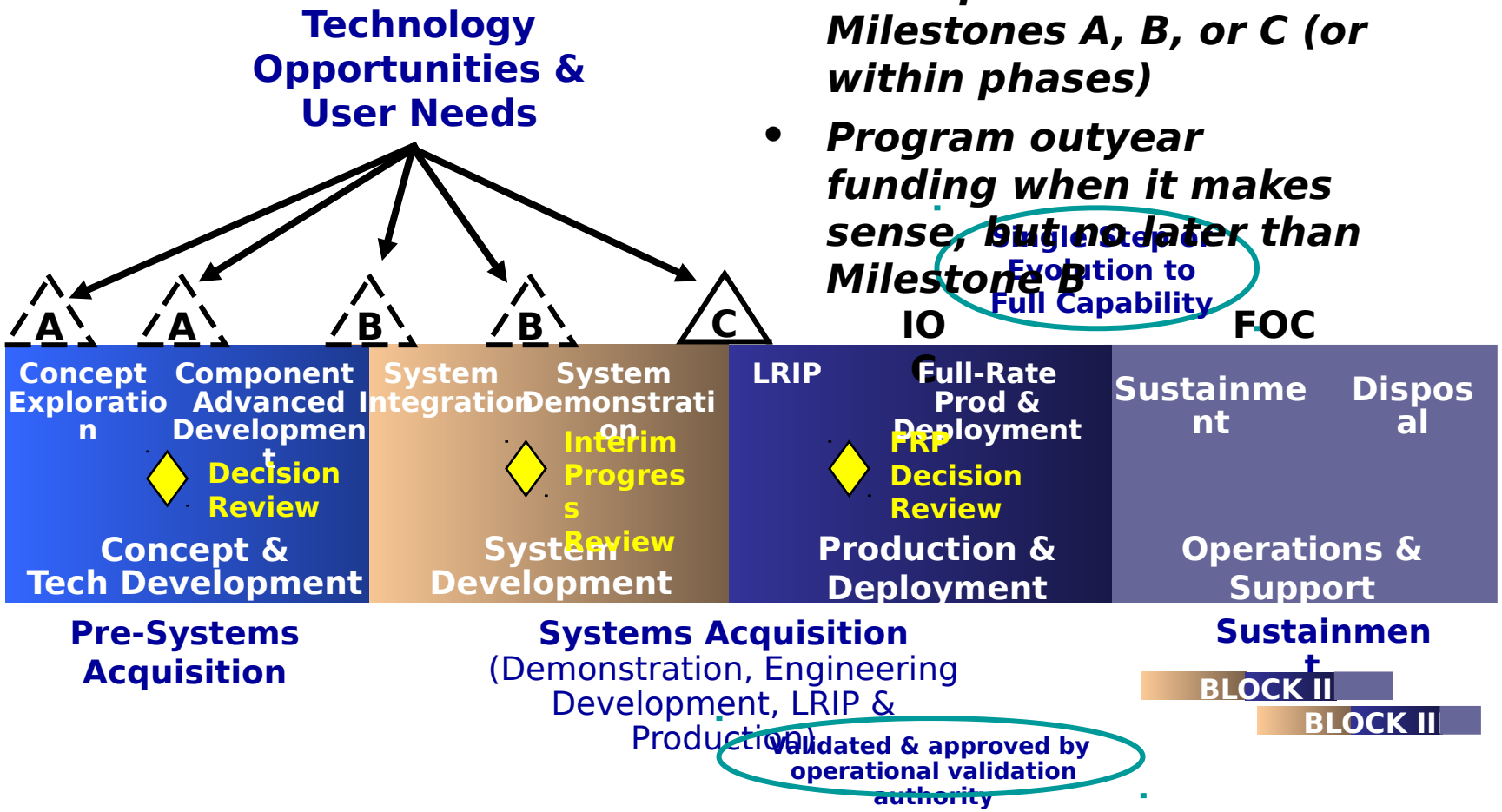
- Integrated, collaborative review process
- Leveraged expertise of all government agencies
- Application of Joint Operating Concepts and integrated architectures.

JCIDS is necessary, but not sufficient!

JCIDS along with the **Defense Acquisition System** and the **Planning, Programming, Budgeting and Execution** process form the principal DOD decision support tools for transforming the military forces to support the national military strategy and the defense strategy

Defense Acquisition Management Framework

- ***Enter process at Milestones A, B, or C (or within phases)***
- ***Program outyear funding when it makes sense, but no later than Milestone B***



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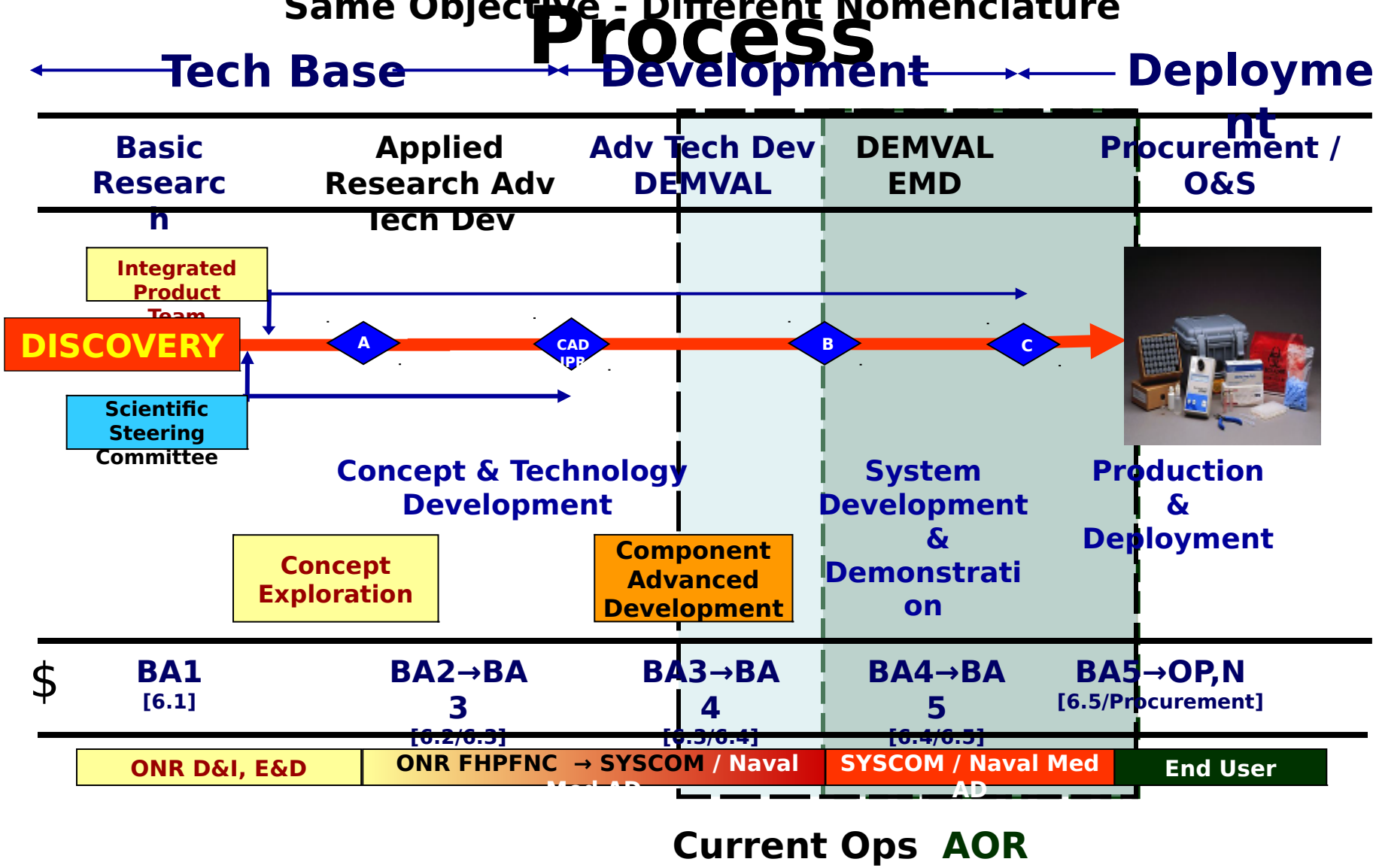
Medical R&D Process

Same Objective - Different Nomenclature



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Budget Activity 5, System Development and Demonstration (SDD). SDD programs have passed Milestone B approval and are conducting engineering and manufacturing development tasks aimed at meeting validated requirements prior to full-rate production. This budget activity includes [illegible] items validated by [illegible] Programs in this budget activity are ready for operational system development. Efforts in this budget activity involve mature system development, integration and demonstration to support Milestone C decisions and conducting live fire test and evaluation (LFT&E) and initial operational test and evaluation (IOT&E) of production representative articles. A logical progression of program phases and development and production funding must be

This means that a *Technology Readiness Level (TRL)* of 6 or 7 has been achieved.

Manual of the Medical Department
U.S. Navy
NAVMED P-117

4 Aug 2005

(e) *Budget Activity 5, System Development and Demonstration (SDD).* SDD programs have passed Milestone B approval and are conducting engineering and manufacturing development tasks aimed at meeting validated requirements prior to full-rate production. This budget activity is characterized by major line item projects and planned operational system levels. Characteristics of this budget activity involve mature system development, integration, and demonstration to support Milestone C decisions, and conducting live fire test and evaluation (LFT&E) and initial operational test and evaluation (IOT&E) of production representative articles. A logical progression of program phases and development and production funding must be evident in the FYDP consistent with the Department's full funding policy.

The Navy Medical Development Program is funded in PE 0604771N and is classified as BA-5 consistent with

***DoD Financial Management Regulation*,**

Volume 2B, Chapter 5, Section 050201, July 2008

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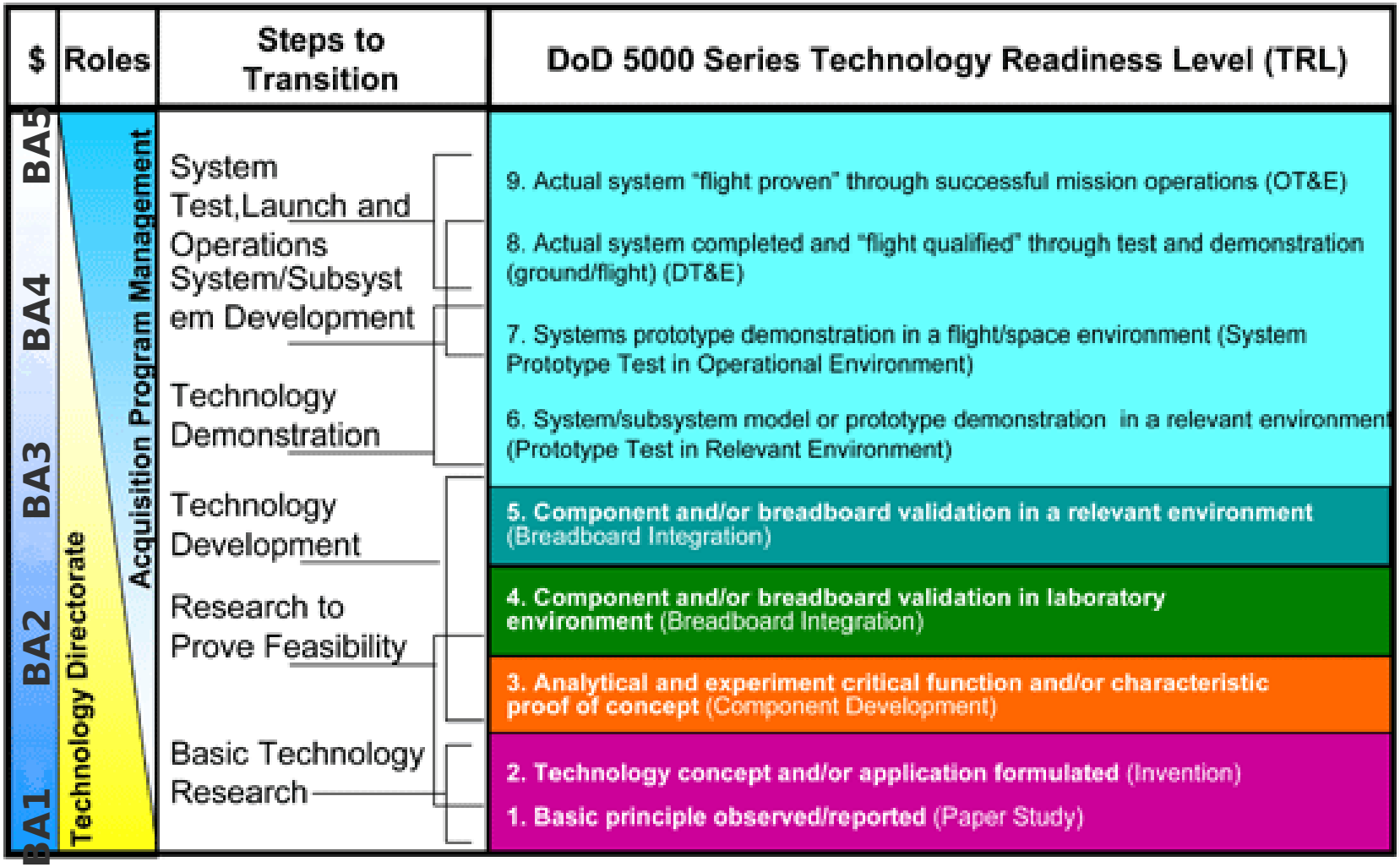
Technology Readiness Level (TRL)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Roles
Steps to Transition
DoD 5000 Series Technology Readiness Level (TRL)
BA5
BA4
BA3
BA2
BA1
Technology Directorate
Acquisition Program Management
System Test,Launch and Operations
System/Subsystem Development
Technology Demonstration
Technology Development
Research to Prove Feasibility
Basic Technology Research
9. Actual system "flight proven" through successful mission operations (OT&E)
8. Actual system completed and "flight qualified" through test and demonstration (ground/flight) (DT&E)
7. Systems prototype demonstration in a flight/space environment (System Prototype Test in Operational Environment)
6. System/subsystem model or prototype demonstration in a relevant environment (Prototype Test in Relevant Environment)
5. Component and/or breadboard validation in a relevant environment (Breadboard Integration)
4. Component and/or breadboard validation in laboratory environment (Breadboard Integration)
3. Analytical and experiment critical function and/or characteristic proof of concept (Component Development)
2. Technology concept and/or application formulated (Invention)
1. Basic principle observed/reported (Paper Study)

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TRLs for Medical RDT&E

DoD Technology Readiness Assessment (TRA) Deskbook

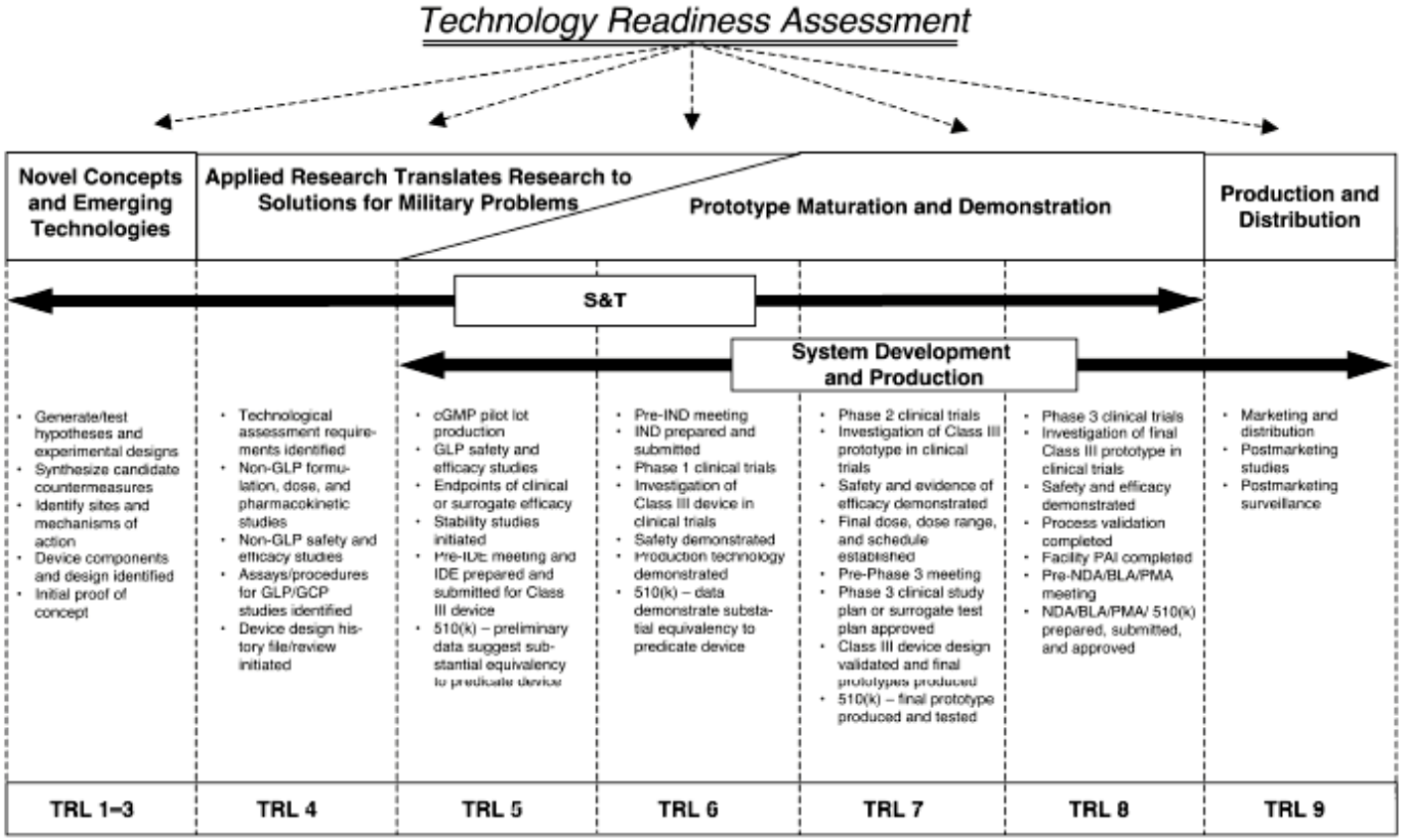
Technology Readiness Assessment
Novel Concepts and Emerging Technologies
Applied Research Translates Research to Solutions for Military Problems
Prototype Maturation and Demonstration
Production and Distribution
S&T
System Development and Production
• Generate/test hypotheses and experimental designs
• Synthesize candidate countermeasures
• Identify sites and mechanisms of action
• Device components and design identified
• Initial proof of concept
• Technological assessment requirements identified
• Non-GLP formulation, dose, and pharmacokinetic studies
• Non-GLP safety and efficacy studies
• Assays/procedures for GLP/GCP studies identified
• Device design history file/review initiated
• cGMP pilot lot production
• GLP safety and efficacy studies
• Endpoints of clinical or surrogate efficacy
• Stability studies initiated
• Pre-IDE meeting and IDE prepared and submitted for Class III device
• 510(k) – preliminary data suggest substantial equivalency to predicate device
• Pre-IND meeting
• IND prepared and submitted
• Phase 1 clinical trials
• Investigation of Class III device in clinical trials
• Safety demonstrated
• Production technology demonstrated
• 510(k) – data demonstrate substantial equivalency to predicate device
• Phase 2 clinical trials
• Investigation of Class III prototype in clinical trials
• Safety and evidence of efficacy demonstrated
• Final dose, dose range, and schedule established
• Pre-Phase 3 meeting
• Phase 3 clinical study plan or surrogate test plan approved
• Class III device design validated and final prototypes produced
• 510(k) – final prototype produced and tested
• Phase 3 clinical trials
• Investigation of final Class III prototype in clinical trials
• Safety and efficacy demonstrated
• Process validation completed
• Facility PAI completed
• Pre-NDA/BLA/PMA meeting
• NDA/BLA/PMA/ 510(k) prepared, submitted, and approved
• Marketing and distribution
• Postmarketing studies
• Postmarketing surveillance
TRL 1–3
TRL 4
TRL 5
TRL 6
TRL 7
TRL 8
TRL 9

Figure H-1. TRLs in the Medical Materiel Regulatory Process

Note for Figure H-1: *The TRL descriptions are not considered absolutes, and characterization of activities associated with TRLs can and does vary at times. The S&T and acquisition PMs work together in exercising discretion in the selection, progression, and timing of specific activities to be accomplished, particularly with regard to TRL 5. Such flexibility and tailoring are needed to align the TRL decision criteria appropriately with maturation and risk characteristics of a particular technology, including consideration of the associated investment strategy and transition procedures that may vary among PMs.*

What Constitutes a Product?

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Table H-1. Proposed TRLs for Medical RDT&E (Continued)

TRL 6 NASA/*Defense Acquisition Guidebook* TRL Definition: System/subsystem model or prototype demonstration in a relevant environment

NASA/ *Defense Acquisition Guidebook* TRL Description	*USAMRMC Equivalent TRL Descriptions*			
	Pharmaceutical (Drugs)[N1, N2]	**Pharmaceutical (Biologics, Vaccines)[N1, N2]**	**Medical Devices[N3, N4]**	**Medical IM/IT & Medical Informatics**
Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment.	Pre-IND meeting (Type B) held with the Center for Drug Evaluation and Research (CDER). IND application is prepared and submitted. Phase 1 clinical trials are conducted to demonstrate safety of candidate in a small number of humans under carefully controlled and intensely monitored clinical conditions. Evaluation of pharmacokinetic and pharmacodynamic data to support the design of well-controlled, scientifically valid Phase 2 studies. Production technologies are demonstrated through production-scale cGMP plant qualification. **TRL 6 Decision Criterion:** Data from Phase 1 trials meet clinical safety requirements and support proceeding to Phase 2 clinical studies.	Pre-IND meeting (Type B) held with the Center for Biologics Evaluation and Research (CBER). IND application is prepared and submitted. Phase 1 clinical trials are conducted to demonstrate safety of candidates in a small number of subjects under carefully controlled and intensely monitored clinical conditions. Evaluation of immunogenicity and/or pharmacokinetics and pharmacodynamics data to support design of Phase 2 clinical trials. Surrogate efficacy models are validated. **TRL 6 Decision Criterion:** Data from Phase 1 clinical trials meet clinical safety requirements and support proceeding to Phase 2 clinical trials.	Clinical trials are conducted to demonstrate safety of candidate Class III medical device in a small number of humans under carefully controlled and intensely monitored clinical conditions. Component tests, component drawings, design history file, design review, and any DMR are updated and verified. Production technology demonstrated through production-scale cGMP plant qualification. For 510(k), component tests, component drawings, design history file, design review, and any DMR are updated and verified. Manufacturing facility is ready for cGMP inspection. **TRL 6 Decision Criterion:** Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and support proceeding to clinical safety and effectiveness trials. For a 510(k), information and data demonstrate substantial equivalency to predicate device and support production of the final prototype and final testing in a military operational environment.	Advanced technical testing of prototype HWIS W system, to include interfaces to actual supporting systems, is conducted in a relevant or simulated operational environment. Out-product is final prototype. **TRL 6 Decision Criterion:** Medical Informatics data and knowledge management systems are tested with target applications in a laboratory environment. Configuration management approach developed.
	Supporting Information	**Supporting Information**	**Supporting Information**	
	For Phase 1 Clinical Trials to begin, the following are needed: the FDA's and sponsor's summary minutes of pre-IND meeting document agreements and general adequacy of information and data to support submission of IND application. Review of the submitted IND application does not result in a FDA decision to put a clinical hold on Phase 1 clinical trials with the candidate drug. For entry into Phase 2 clinical trials, the results from Phase 1 clinical studies have to demonstrate safety of candidate drug. An updated IND application, amended with a new clinical protocol to support Phase 2 clinical trials or a surrogate test plan and submitted to the FDA, documents the achievement of this criterion.	For Phase 1 Clinical Trials to begin, the following are needed: the FDA's and sponsor's summary minutes of pre-IND meeting document agreements and general adequacy of information and data to support submission of an IND application. Review of the submitted IND does not result in an FDA decision to put a clinical hold on Phase 1 clinical trials with the candidate biologic/vaccine. For entry into Phase 2 clinical trials, the results from Phase 1 clinical studies have to demonstrate safety of candidate biologic/vaccine. An updated IND, amended with a new clinical protocol to support Phase 2 clinical trials or surrogate test plan and submitted to the FDA, documents achieving this criterion.	Documentation from clinical study results shows the candidate device is safe. Changes to the investigational plan that require FDA approval (21CFR812.35) are submitted as a supplemental IDE application to the FDA. For a 510(k), reviewers confirm adequacy of documented component tests, component drawings, design history file, design review, and any DMR to support claim of substantial equivalency and readiness for final testing in a military operational environment.	

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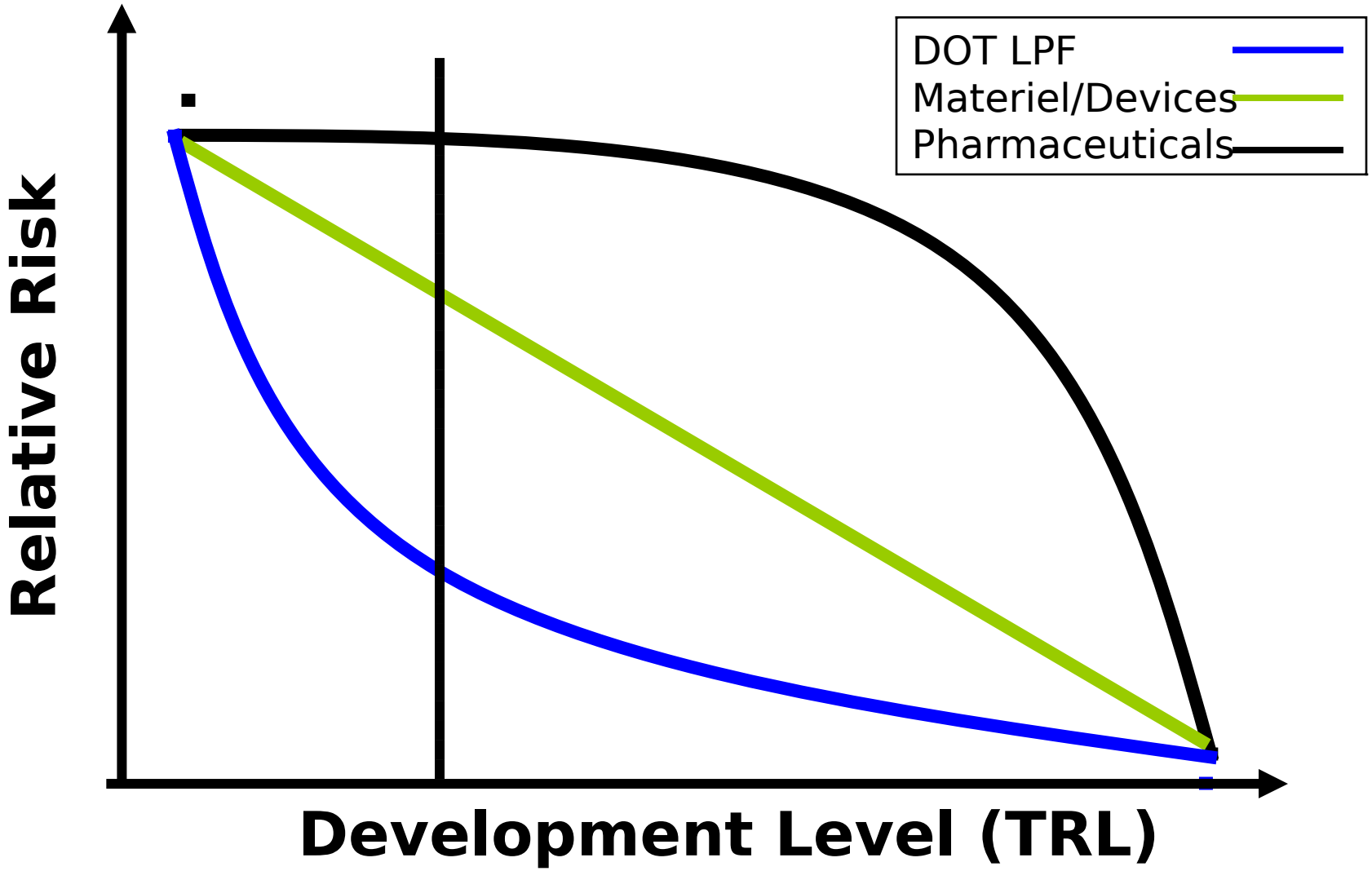
Product Development Pathway & Risk Management



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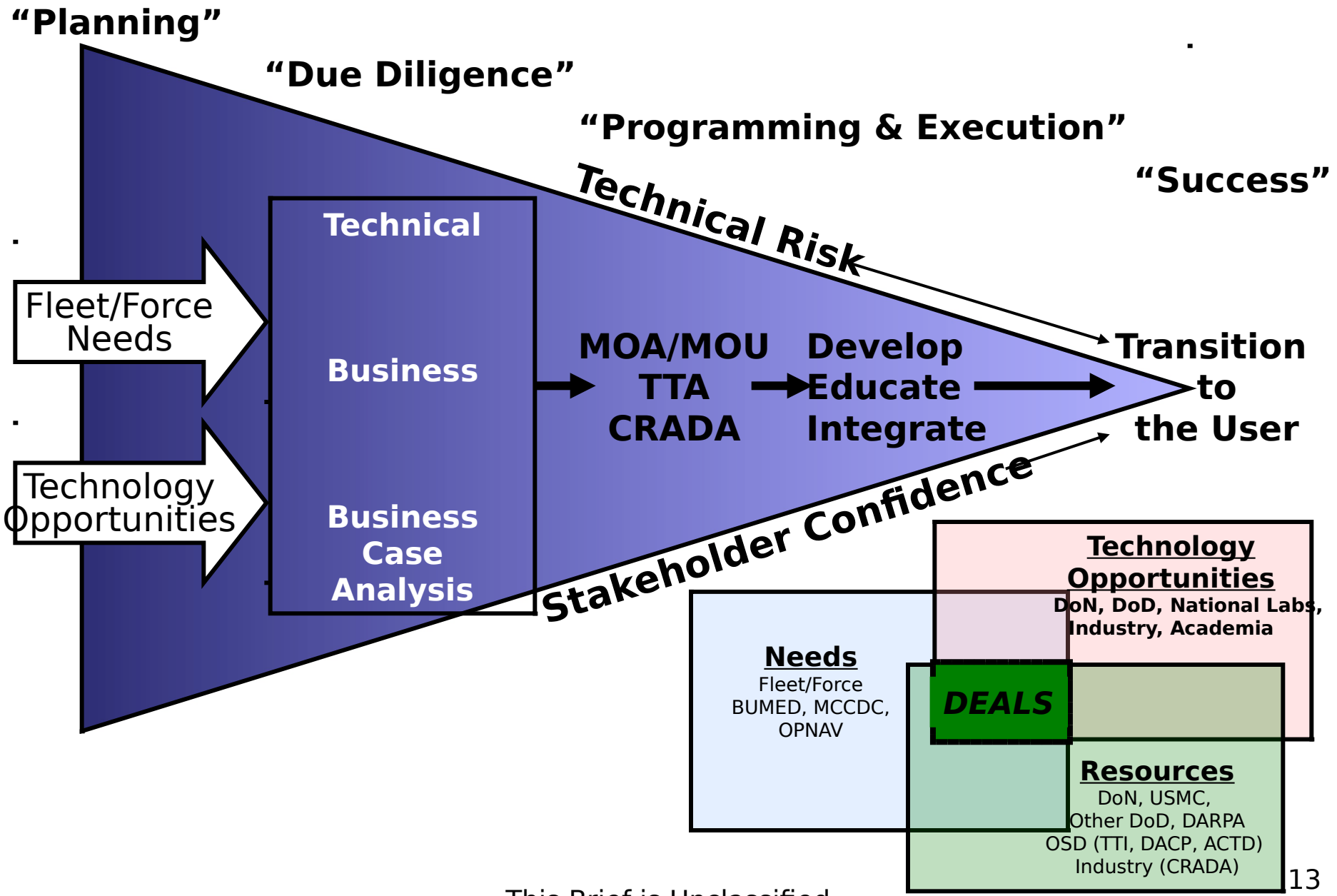
Getting to the Solution



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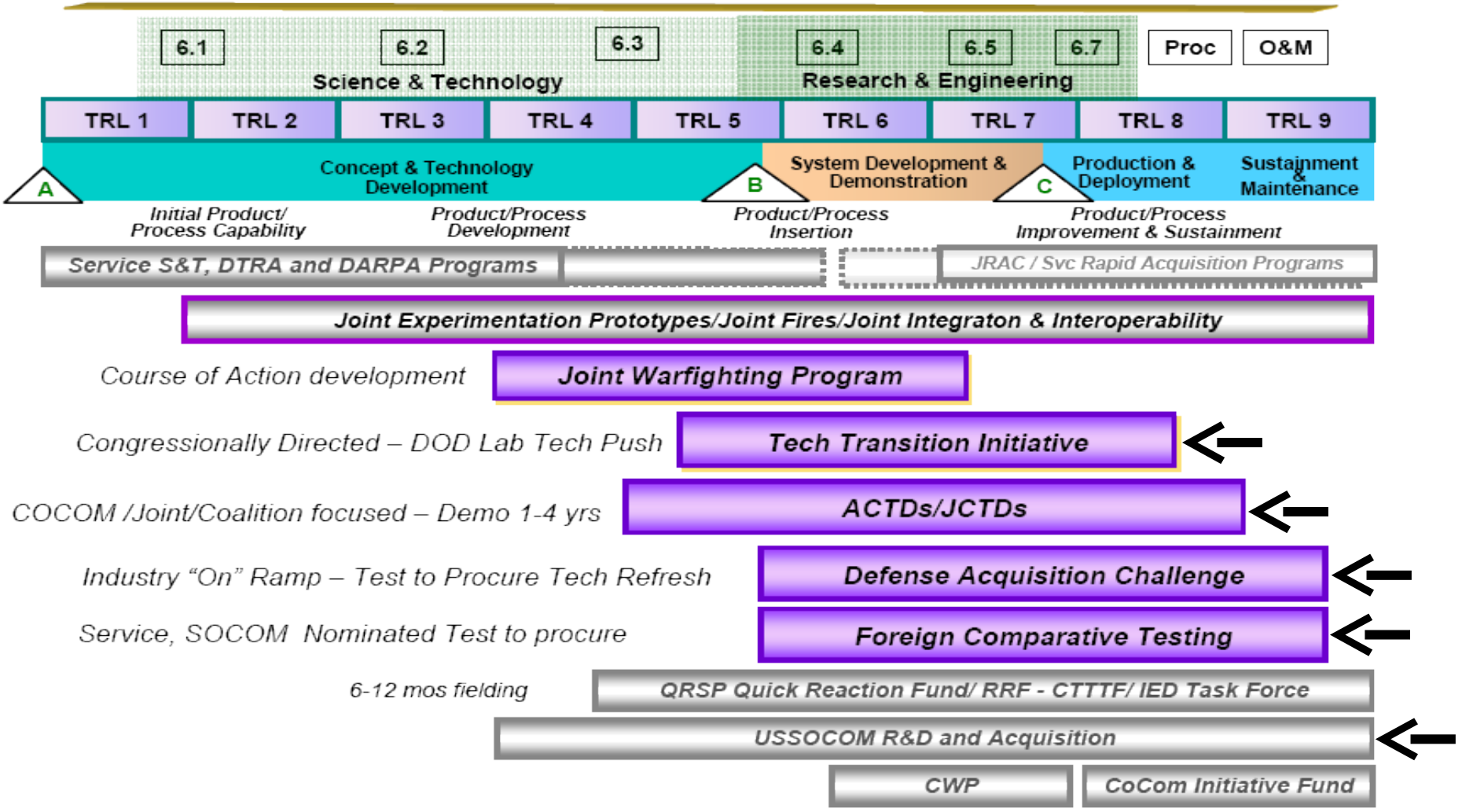
Medical Development Program
Partnering Opportunities

Agile Acquisition Processes



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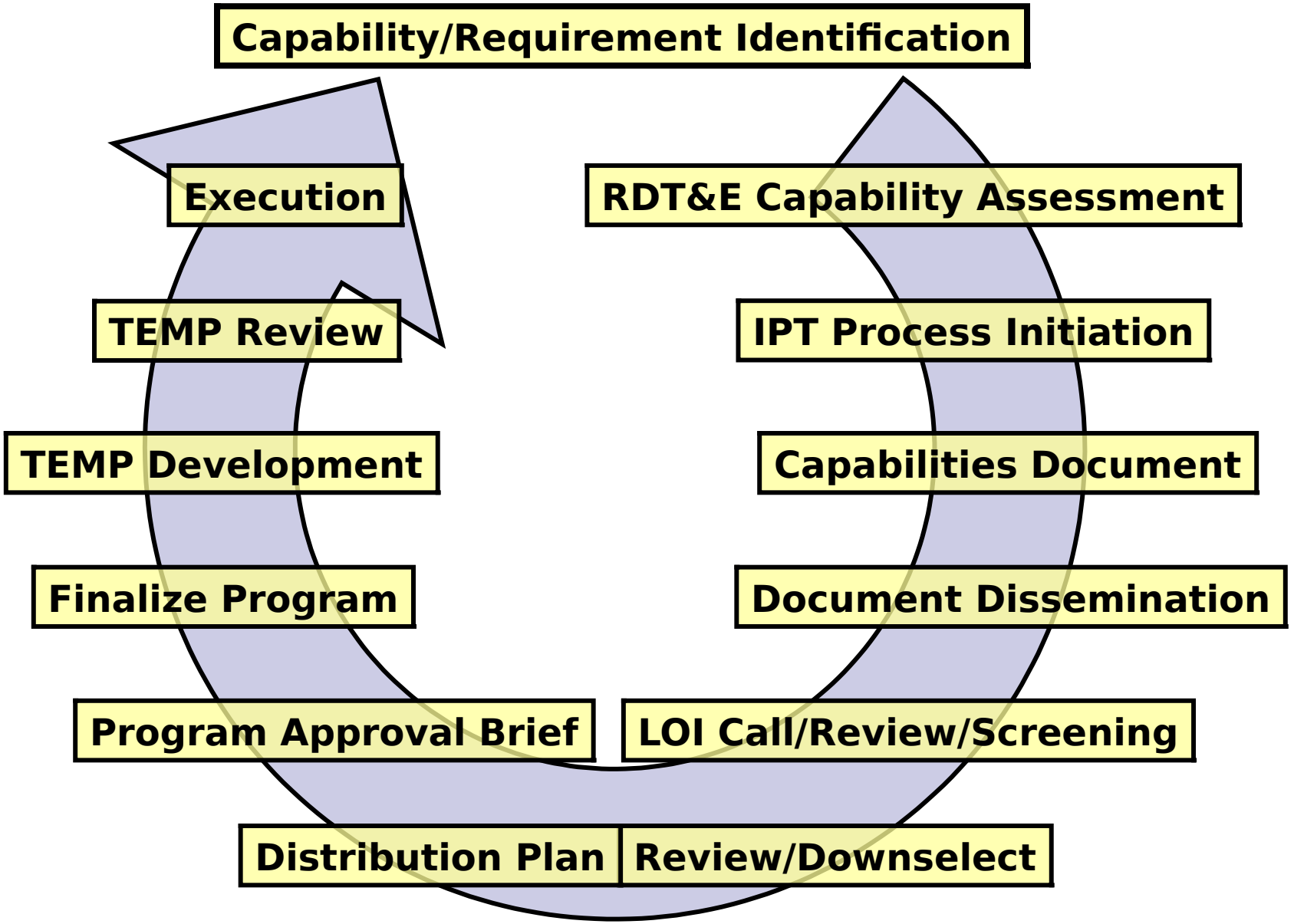
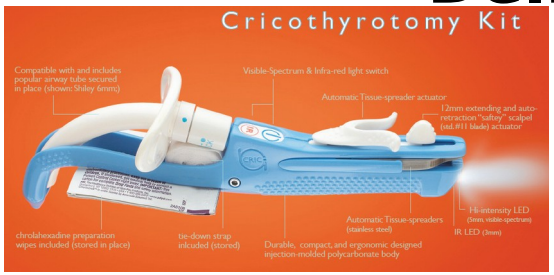
rogram Planning and Execution Cycl



Medical Development Program

Delivery On the Horizon

CyberCric
FY09

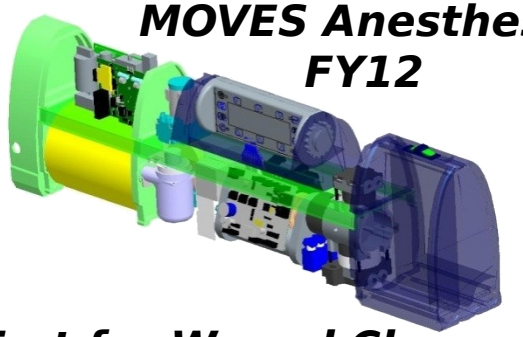

Cricothyrotomy Kit
Compatible with and includes popular airway tube secured in place (shown: Shiley 6mm)
Visible-Spectrum & Infra-red light switch
Automatic Tissue-spreader actuator
12mm extending and auto-retraction "saftey" scalpel (std.#11 blade) actuator
Hi-intensity LED (5mm, visible-spectrum)
IR LED (3mm)
Automatic Tissue-spreaders (stainless steel)
chrolahexadine preparation wipes included (stored in place)
tie-down strap inlcuded (stored)
Durable, compact, and ergonomic designed injection-molded polycarbonate body

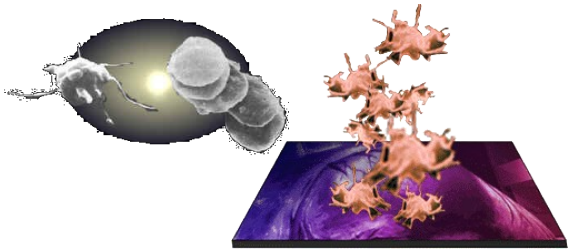
Injectable Hemostatic
FY12

Limb Salvage
FY15+

MOVES
FY09

MOVES Anesthesia
FY12





Test for Wound Closure
FY11

Medical Development Program

What are your questions

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